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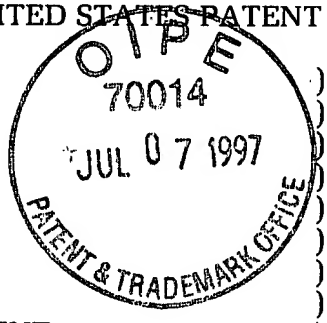
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re patent of:

Cesare Gianturco

Patent No. 5,041,126

Issued August 20, 1991

ENDOVASCULAR STENT
AND DELIVERY SYSTEM

CERTIFICATION

Hon. Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
Sir:

I hereby certify that the attached is a true and accurate copy of the APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156 with attached exhibits and the DECLARATION IN SUPPORT OF APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156 filed this date with the Honorable Assistant Commissioner for Patents.

Dated: JULY 3, 1997

C. David Emhardt

C. David Emhardt
Reg. No. 18,483
Woodard, Emhardt, Naughton
Moriarty & McNett
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456

Attorneys for Cook Incorporated

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on JULY 3, 1997
(Date of Deposit)
CHRISTOPHER A. BROWN
Name of Registered Representative
Signature
JULY 3, 1997
Date of Signature

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Cesare Gianturco

Patent No. 5,041,126

Issued August 20, 1991

ENDOVASCULAR STENT AND DELIVERY SYSTEM

DECLARATION IN SUPPORT OF APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156

Hon. Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

Sir:

I, C. David Emhardt, Esq., Reg. No. 18,483, hereby declare that I am an authorized agent for Cook Incorporated, who has general authority from Cook Incorporated to act on its behalf in patent matters; that I have reviewed and understand the contents of the Application for Extension of Patent Term under 35 U.S.C. §156 being filed herewith; that I believe U.S. Patent No. 5,041,126 is subject to extension pursuant 35 U.S.C. §156 and 37 C.F.R. §1.710; that I believe an extension of the term of the length claimed in the Application being submitted herewith is fully justified under 35 U.S.C. §156 and 37 C.F.R. §§1.710-.785; and that I believe U.S. Patent No. 5,041,126 meets the conditions for extension of its term as set forth in 37 C.F.R. §1.720.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and

further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent term extension issuing thereon.

JULY 3, 1997
Date

C. David Emhardt

C. David Emhardt
Reg. No. 18,483
Woodard, Emhardt, Naughton
Moriarty & McNett
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
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(Date of Deposit)

CHRISTOPHER A. BROWN
Name of Registered Representative

Signature

JULY 3, 1997
Date of Signature

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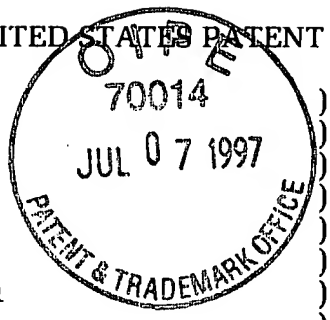
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re patent of:

Cesare Gianturco

Patent No. 5,041,126

Issued August 20, 1991

ENDOVASCULAR STENT
AND DELIVERY SYSTEM

APPLICATION FOR EXTENSION OF PATENT TERM
UNDER 35 U.S.C. §156

Hon. Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231
Sir:

Pursuant to the provisions of 35 U.S.C. §156, and in compliance with 37 C.F.R. §§1.710–.785, Cook Incorporated, a corporation of the State of Indiana having its principal place of business located at 925 South Curry Pike, P. O. Box 489, Bloomington, Indiana 47402, and the owner of record of the above-cited patent, by its undersigned agent, hereby makes application for an extension of the patent term of its United States Patent No. 5,041,126, from March 13, 2007, to February 16, 2008, in accordance with the following.

(1) The approved product that is the subject of this application is a medical device subject to regulation under the Federal Food, Drug, and Cosmetic Act and is indicated for treatment of acute or threatened closure in patients with failed interventional therapy in vessels with reference diameters in the range of 2.1 mm to 4.0 mm, comprising the following unit: Cook GRII^{TM} Coronary Stent.

(2) The regulatory review of the approved product was conducted by the Center for Devices and Radiological Health of the Food and Drug Administration under Sections 515 and 520 of the Federal Food, Drug, and Cosmetic Act.

(3) By letter dated May 12, 1997, the Office of Device Evaluation of the Center for Devices and Radiological Health granted permission to begin commercial distribution of the approved product.

(4) This Application is being submitted within the sixty-day (60) period permitted for submission of such applications for extension of patent terms pursuant to 35 U.S.C. §156(d)(1), and 37 C.F.R. §1.720(f), the last day of said sixty-day (60) period being July 10, 1997, which is the last day upon which this Application could be timely submitted.

(5) United States Patent No. 5,041,126 for an "Endovascular Stent and Delivery System" is the patent for which a term extension is being sought. Application Serial No. 07/244,669 was filed on September 14, 1988 as a continuation of application Serial No. 07/25,736, filed March 13, 1987. Application Serial No. 07/244,669 issued as U.S. Patent No. 5,041,126 on August 20, 1991, in the name of Cesare Gianturco with Cook Incorporated as Assignee. Assignee Cook Incorporated filed a terminal disclaimer during prosecution of U.S. Patent No. 5,041,126, disclaiming its terminal part which would extend beyond the expiration date of U.S. Patent No. 4,800,882, filed March 13, 1987 and issued January 31, 1989. Pursuant to 35 U.S.C. § 154(a)(2), the expiration date of U.S. Patent No. 4,800,882, and therefore the expiration date of U.S. Patent No. 5,041,126, is March 13, 2007.

(6) A copy of United States Patent No. 5,041,126, including the entire specification (including claims) and drawings, is appended hereto.

(7) Also attached hereto are the following:

(a) a copy of a Maintenance Fee Statement receipt received on April 6, 1995; and

(b) a copy of the terminal disclaimer filed during prosecution of U.S. Patent No. 5,041,126.

There are no other disclaimers, certificates of correction, receipts of maintenance fee payments, or re-examination certificates that have issued to date with respect to United States Patent No. 5,041,126.

(8) United States Patent No. 5,041,126 claims the approved product identified in paragraph (1) above, and following is a showing which lists each applicable claim of said Patent and demonstrates the manner in which each applicable claim of said Patent reads on the approved product or on a method of manufacturing or using the approved product.

The Cook GRII^{TM} Coronary Stent is a stainless steel tubular stent intended for percutaneous insertion into vessels using a balloon catheter, according to claims 1 through 3 of U.S. Patent No. 5,041,126. It is indicated for treatment of acute or threatened closure of a vessel by expanding or maintaining an open passageway through the vessel. The following demonstrates the manner in which those claims read on the approved product or on a method for manufacturing or using the approved product:

(a) Claim 1 reads on the method for use of the Cook GRII^{TM} Coronary Stent as follows:

"[E]ngaging a stent . . . around a balloon catheter" is performed with the Cook GRII^{TM} Coronary Stent. After manufacture of the stent, a balloon catheter is inserted longitudinally into the GRII^{TM} Coronary Stent. The stent is

then tightly fitted around the balloon portion of the catheter. The engagement of the stent with the catheter permits introduction of the stent/catheter combination into a vessel and maneuvering therein without dislodging the stent.

"[L]ocating the catheter and stent within a passageway" is performed with the GRII stent. The catheter is inserted into the patient's body and is used to locate the stent within a body passageway. The catheter is guided through the body so that the stent attached thereto is delivered to the desired place, such as a part of a vessel subject to acute or threatened closure.

"[I]nelastically expanding the stent . . . by inflating the balloon catheter" is performed with the GRII stent. When the stent is at the desired location, the balloon portion of the catheter is inflated, thereby inelastically expanding the stent radially, but not longitudinally, to engage the body passageway. The balloon engages the loops of curved metal which form the tubular stent and forces them radially outward.

(b) Claim 2 reads on the Cook GRII^{TM} Coronary Stent as follows:

"[A] tubular shaped stent . . . having a first diameter" is provided by the Cook GRII^{TM} Coronary Stent. The stent is formed by numerous elongated stainless steel members curved in the shape of a tube. Pairs of these curved elongated members are connected by rounded cusps, making loops, and the elongated members are also connected to a longitudinal strip or spine. The curved elongated members remain in a tubular shape, with a first diameter, until acted upon by the balloon catheter within it.

"[A] portion of said tubular shaped stent having a second, expanded diameter" is also provided by the Cook GRII^{TM} Coronary Stent. The stent is tightly fitted around a balloon catheter and is inserted into a body vessel. The

catheter is maneuvered through the body so as to place the stent at a desired location. At the desired location, the balloon is inflated, providing an outwardly directed force on the inside of the curved elongated members of the stent. At least a portion of these elongated members, and therefore a portion of the stent, is expanded inelastically, with no change in the length of the stent. The expanded portion engages the walls of the body passageway, thereby expanding the lumen. The stent, with its expanded diameter, is retained in the body passageway when the balloon is deflated.

(c) Claim 3 reads on the method of use of the Cook GRII^{TM} Coronary Stent as follows:

"[I]nserting an endovascular stent . . . disposed on a catheter into the body passageway" is performed in the use of the GRII stent. The stent is tightly fitted around the balloon portion of a balloon catheter. The balloon catheter is inserted into a body passageway and is used to move the stent to a desired location within the lumen of a body passageway.

"[E]xpanding a portion of the catheter to expand the endovascular stent" is also performed. When the stent is at the desired location, the balloon portion of the catheter is inflated, engaging the curved elongated members of the stent and inelastically expanding them. The radius of the stent is extended, but not the length, so that the stent contacts the body passageway and expands the lumen therethrough. The expanded stent is retained in the body passageway after the balloon catheter has been removed, thereby preventing the collapse of the passageway.

(9) The relevant dates and information pertinent to 35 U.S.C. §156(g) and 37 C.F.R. §1.740(a)(10)(v), which are being provided in order to enable the Secretary of Health and Human Services to determine the applicable "regulatory review period," follow:

12/20/95	The effective date of investigational device exemption (IDE) #G950163
01/24/96	The first clinical implant under IDE #G950163
11/23/96	The date on which an application for product approval was initially submitted under PMA #910030
05/12/97	The date PMA #910030 was approved

(10) A brief description of the activities undertaken during the applicable "regulatory review period" with respect to the approved product, and the significant dates applicable to such activities, follow:

09/27/95	Submission of Investigational Device Exemption (IDE) supplement for the GRII™ Coronary Stent
10/02/95	Notification by FDA of receipt of IDE submission, assigned new number G950163
10/27/95	Notification of disapproval of IDE by FDA
11/09/95	Discussion with FDA of deficiency questions for GRII trial
12/01/95	Submission of first IDE amendment in response to FDA's request for additional information
12/20//95	Notification by FDA of conditional approval of IDE #F950163, pending amendment of hypothesis
01/02/96	Submission of response to FDA's notification of 12/20/95
01/02/96	Submission of supplement to FDA regarding physician "learning curve" and increasing investigative sites from 30 to 50.
01/24/96	First clinical implant under IDE #G950163
01/25/96	Notification by FDA that IDE #G950163 is approved and study may continue at the 30 investigational sites
01/25/96	Notification by FDA that supplement of 1/02/96 is approved--study is increased to 50 investigational sites
02/27/96	Submission of supplement for low molecular weight heparin
03/05/96	Discussion of IDE supplement of 02/27/96
03/06/96	Submission of corrected letter for the IDE supplement of 02/27/96
04/12/96	Sent summary of investigators' meetings to all investigators, co-investigators & research coordinators of GRII clinical trial
05/13/96	Submission of IDE supplement requesting additional patients in Small Caliber Vessel Registry
05/22/96	Discussion with FDA regarding status of request for additional patients into closed trial registries

05/24/96	Submission of supplement regarding compassionate use of GRII
05/30/96	Submission of supplement requesting addition of 4.5 & 5.0 mm GRII stents to trial
05/31/96	Notification by FDA of approval of additional patients into small vessel and acute and threatened closure registries for clinical trial
06/06/96	Submission of supplement regarding deviations from protocol and informed consent
06/19/96	Letter disapproving the IDE supplement of 05/30/96
07/03/96	Letter from Cook Incorporated requesting additional patients in acute and threatened closure registry
07/24/96	Letter from Cook Incorporated requesting additional patients in small vessel registry
07/24/96	Notification of FDA approval allowing 200 additional patients to be enrolled in acute and threatened closure registry
09/20/96	Facsimile from Cook Incorporated regarding status of trial, pulling devices from the centers, timing of randomized submission for elective patients, and submission of registry data
10/09/96	Discussion with FDA regarding trial update, acute and threatened closure submission, request for more acute and threatened closure patients
10/23/96	Submission of draft format Pre-Market Approval (PMA) supplement, with comments specifically requested
10/28/96	Discussion with FDA regarding response to PMA correspondence and FDA request for more tables
10/30/96	Facsimile from Cook Incorporated regarding changes to draft clinical summary
11/04/96	Discussion with FDA regarding suggestions and changes to PMA supplement
11/05/96	Letter from Cook Incorporated requesting additional patients in acute and threatened closure registry
11/21/96	Letter from Cook Incorporated requesting permission for Dr. Colombo to perform live cases with the GRII stent at the 14th annual International Interventional Cardiology Symposium
11/23/96	Submission of PMA supplement (#P910030) for GRII stent

11/26/96	Acknowledgement by FDA of receipt of PMA supplement
12/04/96	Notification of approval of an additional 200 patients in acute and threatened registry
12/18/96	Notification of conditional approval of IDE supplement proposing treatment of three patients at the Miami Heart Institute for demonstration purposes during the 14th annual International Interventional Cardiology Symposium
12/24/96	Submission of amendment of the Clinical Summary "Panel Pack" for PMA supplement #P910030 requesting approval of the second generation Gianturco-Roubin Coronary Stent (GRII™) for the indication of acute and threatened closure
12/26/96	Notification by FDA of receipt of amendment of 12/24/96
01/09/97	Acknowledgement by FDA of receipt of PMA amendment of 12/24/96
01/29/97	Discussion with FDA regarding stent trial and submission to FDA
02/07/97	Discussion with FDA regarding status of PMA submission
02/12/97	Notification of conditional approval of IDE supplement proposing treatment of up to six patients for demonstration purposes during two symposiums
03/11/97	Discussed questions regarding FEA analysis of stent
03/11/97	Facsimile from Cook Incorporated regarding response to original IDE deficiency letter and fatigue testing
03/13/97	Discussion with FDA regarding endurance limit of stent
03/17/97	Submission of final labeling to FDA
03/18/97	Acknowledgement by FDA of receipt of PMA amendment (final labeling)
03/21/97	Facsimile from Cook Incorporated regarding additional information with respect to the fatigue analysis
03/31/97	Discussion with FDA regarding patient data and endurance limit testing
03/31/97	Discussion with FDA regarding mechanical testing of stent spine
04/16/97	Discussion with FDA regarding endurance testing, new modulus rating, bending angles, and clinical studies
04/17/97	Discussion with FDA regarding labeling/deficiency letter for fatigue testing

04/25/97	Submission of amendment of PMA #P910030 requesting approval of the second generation Gianturco-Roubin Coronary Stent (GRII ™) for the indication of acute and threatened closure
04/29/97	Acknowledgement by FDA of receipt of PMA amendment requesting approval of GRII stent for acute and threatened closure
05/02/97	Discussion with FDA regarding calculations on material properties
05/02/97	Submission of supplement requesting treatment of 3 patients for demonstration purposes during the "New Horizons" interventional cardiovascular symposium
05/02/97	Notification of approval of supplement requesting treatment of 3 patients for demonstration purposes during the "New Horizons" interventional cardiovascular symposium
05/07/97	Submission of response to FDA letter of 2/12/97 regarding live cases performed at the International Congress X Symposium in Phoenix
05/12/97	Approval of PMA supplement for acute or threatened closure

(11) In the opinion of Cook Incorporated, U.S. Patent No. 5,041,126 is eligible for an extension of its term as herein requested, and a statement as to the length of the term extension requested, including how the length of the extension was determined, follows:

An extension of the term of U.S. Patent No. 5,041,126 of three hundred forty-one (341) days from March 13, 2007 (the original expiration date), to and including February 16, 2008, is being requested hereby.

As noted in paragraph 5, above, the terminal part of U.S. Patent No. 5,041,126 extending beyond the expiration date of U.S. Patent No. 4,800,882 has been dislcaimed. Pursuant to 35 U.S.C. § 154(a)(2), the expiration date of U.S. Patent No. 4,800,882 is twenty years from its filing date of March 13, 1987. Accordingly, the expiration date of U.S. Patent No. 4,800,882, and therefore of U.S. Patent No. 5,041,126, is March 13, 2007.

Pursuant to 35 U.S.C. §156(c), the term of a patent eligible for extension under §156(a) shall be extended by the time equal to the "regulatory review period" (as defined in §156(g)) for the approved product that occurred after the patent issued. Section 156(c) sets forth four (4) exceptions: (1) the eligible period is reduced by any period during which applicant did not act with due diligence (there is no such period believed to be pertinent herein); (2) after deductions, if any, under (1), the remaining period calculated under §156(g)(3)(B)(i) (for approved products that are medical devices) is reduced by one-half (1/2); (3) the sum total of the remaining original term of the patent after product approval and the "regulatory review period" (as defined in §156(g)) may not exceed fourteen (14) years; and (4) only one (1) patent may be extended for the same regulatory review period.

The applicable "regulatory review period" herein is calculated under §156(g)(3)(A) and (B), by taking one-half of the period calculated under §156(g)(3)(B)(i) and adding thereto the period calculated under §156(g)(3)(B)(ii), as follows (see paragraphs (9)-(10), supra):

The date clinical investigations on humans involving the device was begun	12/20/95
The date an application was initially submitted with respect to the device under section 515	11/23/96
Intervening period (i)[§156(g)(3)(B)(i)]	340 days
One-half (1/2) of Intervening period (i)	**170 days**
The date an application was initially submitted with respect to the device under section 515	11/23/96
The date such application was approved	5/12/97
Intervening period (ii)[§156(g)(3)(B)(ii)]	**171 days**

The maximum "regulatory review period" to which Cook Incorporated is entitled under §156(c) is believed to be the sum of one-half (1/2) of intervening period (i) plus the full intervening period (ii), or 170 days + 171 days = 341 days. As no other provisions limiting the term of extension are believed to be applicable, Cook Incorporated believes it is entitled to an extension of the term of U.S. Patent No. 5,041,126 of 341 days, to and including February 16, 2008.

(12) Cook Incorporated acknowledges its duty to disclose to the Commissioner of Patents and Trademarks and to the Secretary of Health and Human Services any information that is material to any determination that is to be made relative to the instant application for extension of patent term.

(13) The prescribed fee of $1,090.00 for receiving and acting upon the instant application for extension of patent term, and the declaration of the undersigned authorized agent of Cook Incorporated supporting the instant application for extension, are appended hereto.

(14) The name, address, and telephone number of the person to whom inquiries and correspondence relating to this application are to be directed is: C. David Emhardt, Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, 111 Monument Circle, Suite 3700, Indianapolis, Indiana 46204-5137, (317) 634-3456.

Respectfully submitted,
COOK INCORPORATED

By C. David Emhardt

C. David Emhardt
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Woodard, Emhardt, Naughton
Moriarty & McNett
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Attorneys for Cook Incorporated

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(Date of Deposit)
CHRISTOPHER A. BROWN
Name of Registered Representative
Signature
JULY 3, 1997
Date of Signature

United States Patent [19]

Gianturco

[11] Patent Number: 5,041,126

[45] Date of Patent: * Aug. 20, 1991

[54] ENDOVASCULAR STENT AND DELIVERY SYSTEM

[75] Inventor: Cesare Gianturco, Champaign, Ill.

[73] Assignee: Cook Incorporated, Bloomington, Ind.

[*] Notice: The portion of the term of this patent subsequent to Jan. 31, 2006 has been disclaimed.

[21] Appl. No.: 244,669

[22] Filed: Sep. 14, 1988

Related U.S. Application Data

[63] Continuation of Ser. No. 25,736, Mar. 13, 1987, Pat. No. 4,800,882.

[51] Int. Cl.[5] A61M 29/02

[52] U.S. Cl. 606/195; 604/104; 623/1

[58] Field of Search 128/341, 343, 344; 604/96, 8, 104; 606/191-200; 623/1, 12, 900

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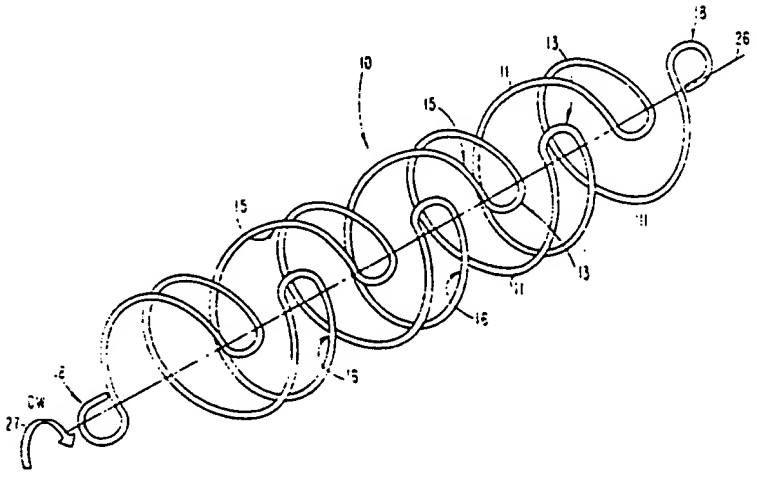
(List continued on next page.)

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Ralph A. Lewis
Attorney, Agent, or Firm—Woodard, Emhardt, Naughton, Moriarty & McNett

[57] ABSTRACT

A wire stent for insertion and expansion into a passageway comprises a plurality of curved sections that are formed into a generally circular configuration. Adjacent curved sections are joined by a bend or cusp, so that a series of alternating opposing loops are formed. The wire stent as formed has a cylindrical shape with a longitudinal opening through which a folded balloon catheter is inserted. The opposing loops are tightly contracted about the catheter so that the cylindrical shape has an overlapping region in which portions of adjacent loops longitudinally overlap. The loops are arranged so that when the balloon catheter is inflated, adjacent loops diverge circumferentially relative to each other, thereby decreasing the overlapping region while increasing the diameter of the cylindrical shape. As the diameter of the cylindrical shape increases, the wire stent contacts the surface of a passageway in which the stent is inserted.

3 Claims, 5 Drawing Sheets



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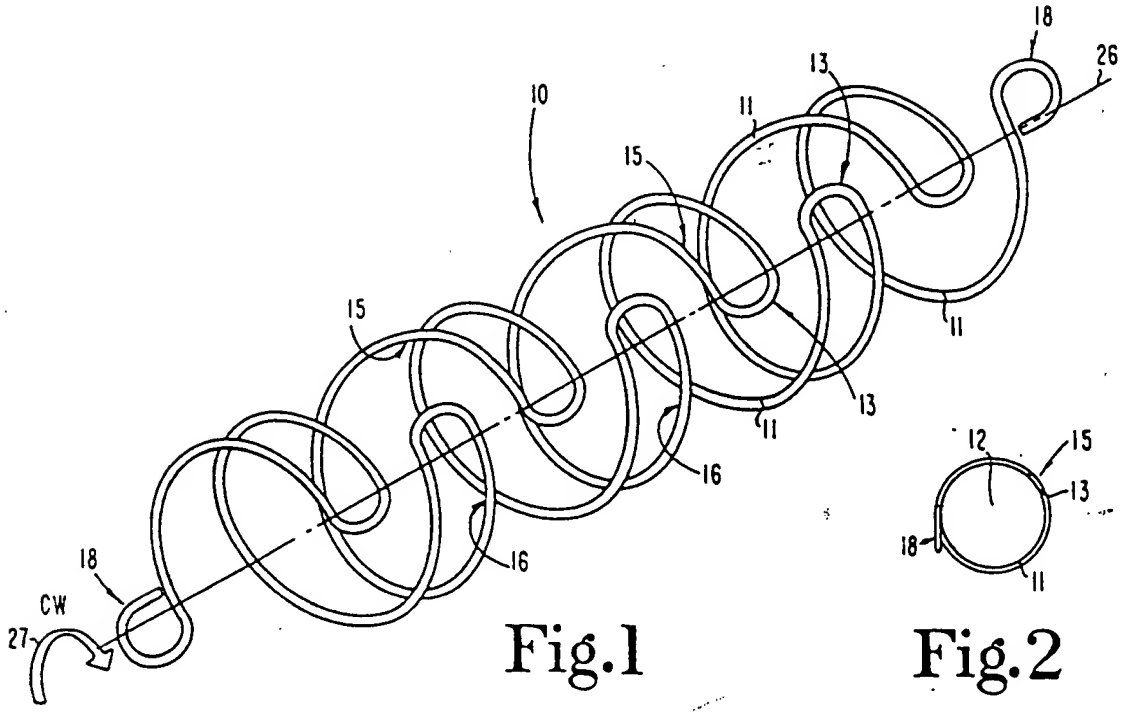

Fig.1

Fig.2

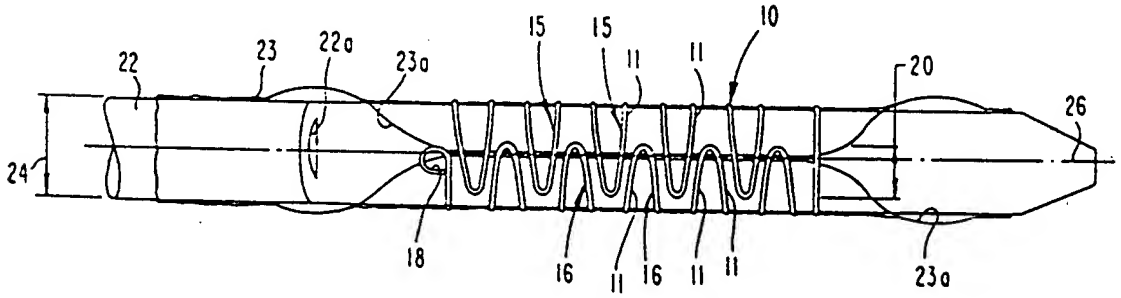

Fig.3

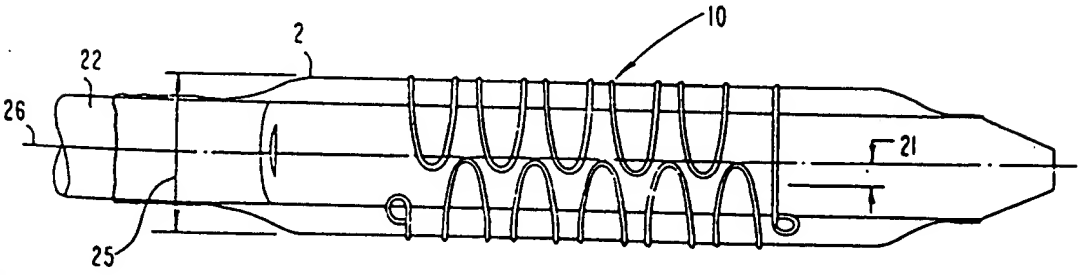

Fig.4

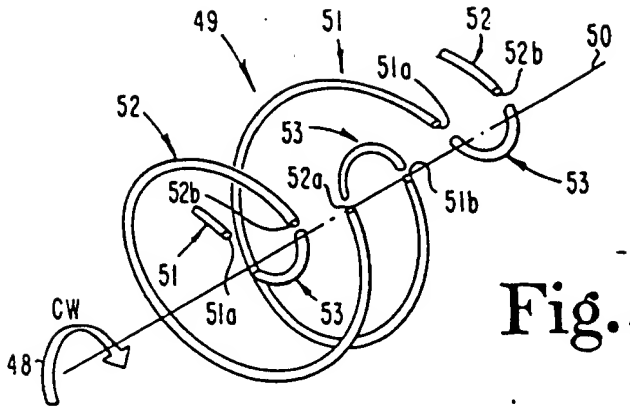
49
51
52
52b
50
51a
52
53
52a
51b
53
52b
51
51a
53
CW
48

Fig.5

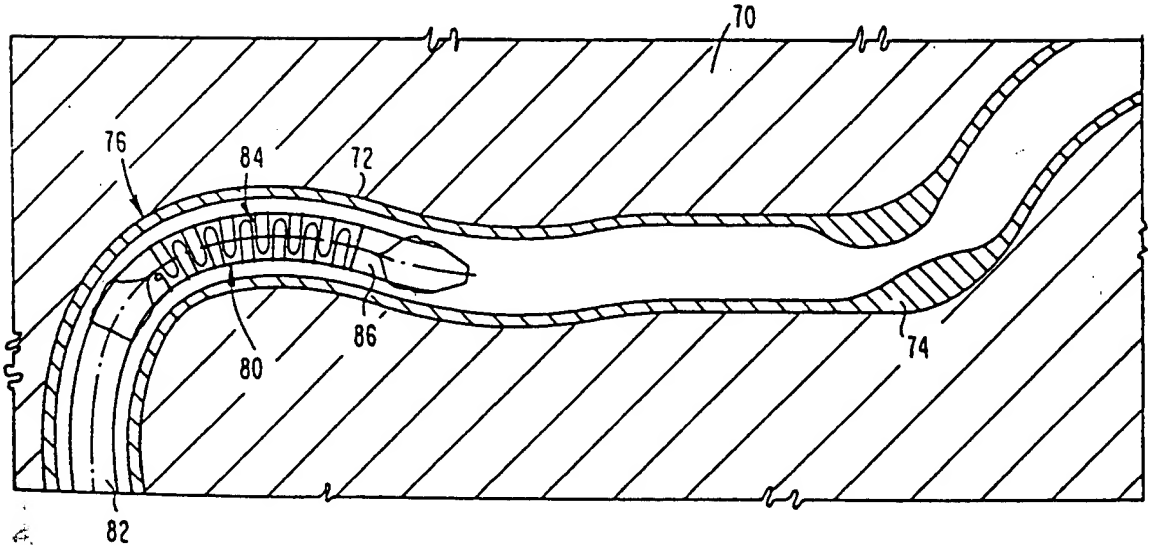
70
76
84
72
80
86
74
82

Fig.6

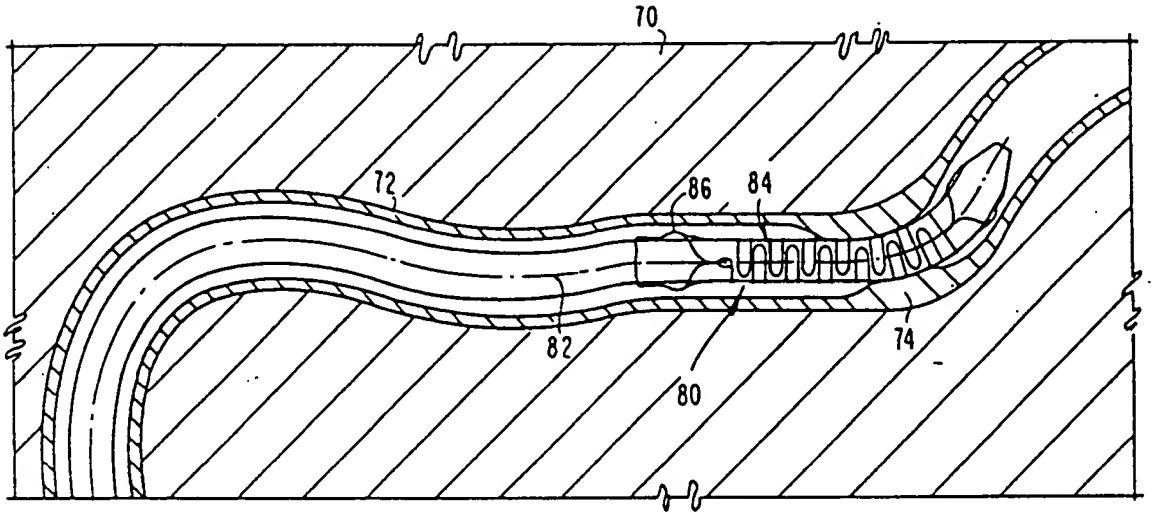

Fig.7

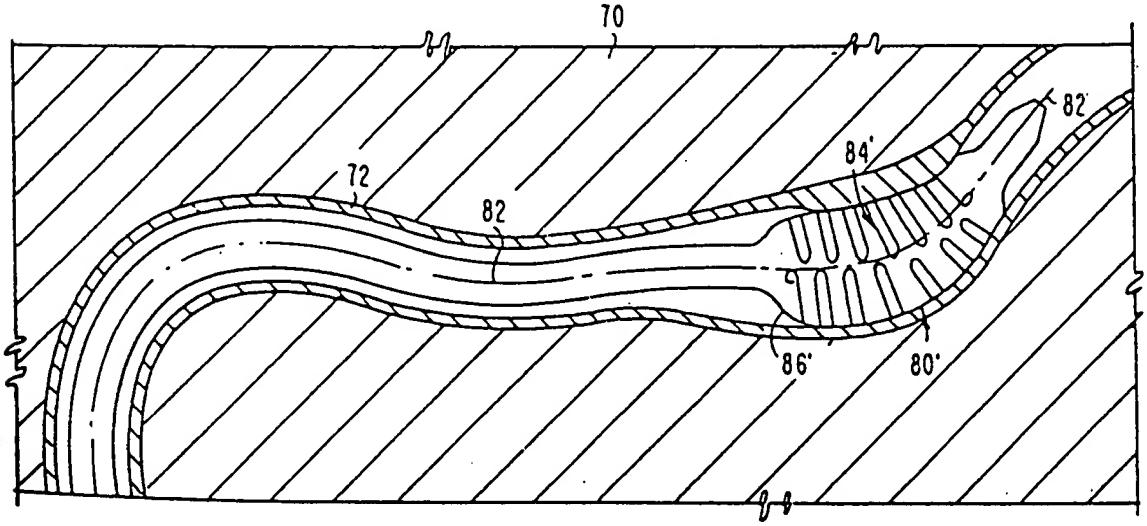

Fig.8

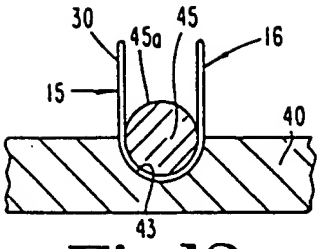

Fig.12

Fig.11

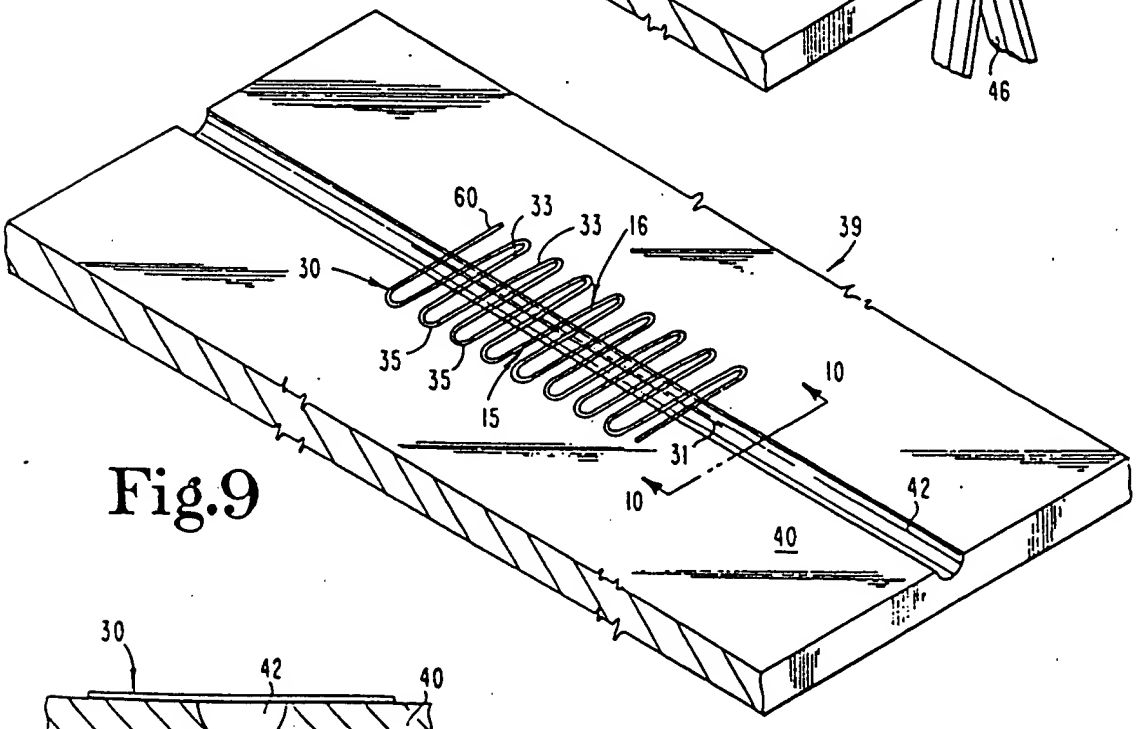

Fig.9

Fig.10

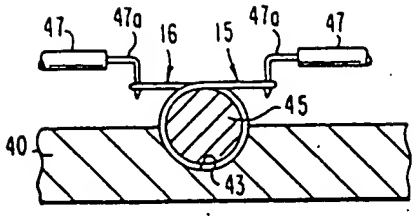

Fig.14

Fig.13

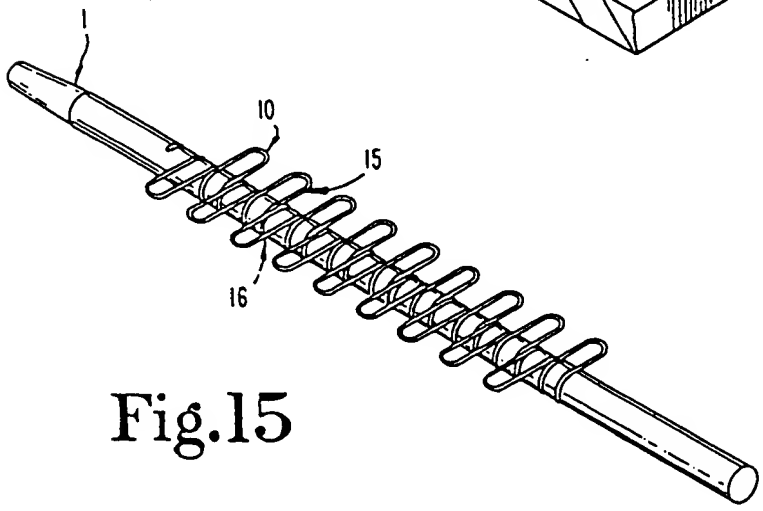

Fig.15

ENDOVASCULAR STENT AND DELIVERY SYSTEM

This application is a continuation of application Ser. No. 025,736, filed Mar. 13, 1987, now U.S. Pat. No. 4,800,882.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to stents and a method for inserting a stent.

2. Description of the Prior Art

It is desirable in various situations to provide means for expanding a constricted vessel or for maintaining an open passageway through a vessel. Such situations arise, for instance, after an angioplasty of a coronary artery. In these situations, wire stents are useful to prevent restenosis of the dilated vessel, or to eliminate the danger of occlusion caused by "flaps" resulting from intimal tears associated with angioplasty. Wire stents can also be used to reinforce collapsing structures in the respiratory and biliary tracts.

Typical of the wire stents of the prior art is the stent of Gianturco, U.S. Pat. No. 4,580,568, wherein the stent is compressed and encased in a sheath. The sheath is then positioned in the vascular system and the stent is held in position by a flat-ended pusher while the sheath is withdrawn. The zig-zag configuration of this particular stent allows it to expand in the passageway to hold the passageway open and enlarged.

Stents comprised of variously shaped spiral springs are described by Maass et al. in U.S. Pat. No. 4,553,545, and in *Radiology Follow-up of Transluminally Inserted Vascular Endoprosthesis: An Experimental Study Using Expanding Spirals.* Radiology. September 1984; 152:659-663. Application of torque to the end of these spiral springs increases the number of coils while decreasing the stent diameter for insertion. Once inserted, an opposite torque is applied to the spiral springs causing the stent diameter to increase. Use of this type of stent requires a sophisticated, coaxial cable to apply torque to the stent once it has been inserted into the vessel.

Dotter et al. reported the use of a prosthesis constructed of a thermal shape memory alloy which is passed into the passageway through a catheter. See, Dotter CT et al., *Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report.* Radiology, April 1983; 147;259-260. This coil stent is compacted by cooling, inserted, and then heated in situ until the stent expands in the passageway. This stent is positioned within the vessel by a detachable positioning device capable of supplying electrical energy to heat the thermal coil.

Other references which may have relevance to the present invention are the following U.S. Pat. Nos.: Absolins, 3,278,176; Alfidi et al., 3,868,956; Simon, 4,425,908; and Sakura, Jr., 4,214,587.

Among the drawbacks of the prior art wire stents and expandable coil stents are that these stents are either difficult to produce or complicated to insert into a body passageway. Each of these stents requires the use of a complex device for insertion and expansion of the stent within the vessel. On the other hand, less complex wire stents lack the axial compliance to pass through a catheter that has any significant curves or bends. The present invention addresses each of these problems by providing a wire stent that is easy to produce, simple to install and capable of delivery around curves and bends in a vessel or passageway.

SUMMARY OF THE INVENTION

A stent comprising a wire formed into a serpentine configuration including a series of straight sections and a plurality of bends. The straight sections are joined by the bends to form a series of alternating loops. The serpentine configuration is formed into a cylindrical shape having a longitudinal axis, wherein the straight sections are bent into generally circular configurations surrounding and generally perpendicular to the longitudinal axis means are provided for expanding the circular configurations and, consequently, the cylindrical shape, comprising a balloon catheter. The balloon catheter is folded and received within the cylindrical shape and extends along the axis of the cylindrical shape. The straight sections are formed about the balloon catheter such that adjacent loops diverge circumferentially relative to each other as the balloon is inflated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a wire stent of the present invention;

FIG. 2 is an end view of the wire stent of FIG. 1.

FIG. 3 is a side view of the wire stent of FIG. 1 engaged around a folded balloon catheter and shown in the contracted condition.

FIG. 4 is a side view of the wire stent and balloon catheter of FIG. 3, shown in the expanded condition.

FIG. 5 is a fragmentary exploded view of a portion of a wire stent of FIG. 1.

FIG. 6 is a cutaway view of a body cavity with the wire stent and balloon catheter situated in a curve in the cavity.

FIG. 7 is the cutaway view similar to FIG. 6 with the stent and balloon catheter situated within the cavity adjacent an occlusion in the cavity.

FIG. 8 is the cutaway of FIG. 7, showing with the balloon catheter inflated and with the stent in contact with the cavity wall to remove the occlusion.

FIG. 9 is a perspective view of a step of a method of the present invention showing a wire formed into a planar serpentine configuration and placed on a forming die.

FIG. 10 is a cross-sectional view of the forming die in FIG. 9 taken along line 10—10 and viewed in the direction of the arrows.

FIG. 11 is a perspective view of the wire pressed into a trough in the forming die by a forming bar.

FIG. 12 is a cross-sectional view of the forming die and forming bar of FIG. 11 taken along line 12—12 and viewed in the direction of the arrows.

FIG. 13 is a perspective view similar to FIG. 11 and showing the loops of the serpentine configuration pulled over the exposed portion of the forming bar by pulling tools.

FIG. 14 is a cross-sectional view of the forming die and forming bar in FIG. 13 taken along line 14—14 and viewed in the direction of the arrows.

FIG. 15 is a perspective of a balloon catheter inserted through a generally cylindrical opening formed by the wire in one step of the present method.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be

made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIG. 1, a wire stent 10 is shown as having a longitudinal axis 26. The stent comprises a plurality of curved sections 11 that are situated generally perpendicular to the axis 26. Adjacent curved sections 11 are joined by bends or cusps 13. A loop 18 is formed at each free end of the wire stent 10 in order to shield the wire end. The curved sections 11 are formed into a circular configuration, as shown in the end view of FIG. 2, so that the stent 10 has a cylindrical opening 12 formed therein.

The curved sections 11 and cusps 13 form a series of alternating clockwise and counter-clockwise loops 15 and 16, respectively. The clockwise direction relative to the axis 26 has been arbitrarily selected and is noted by the heavy arrow 27 in FIG. 1. In the contracted condition of the stent 10, these loops 15 and 16 overlap longitudinally, as demonstrated by the overlap region 20 shown in FIG. 3. Thus, the overlap region 20 gives the appearance that the stent is a continuous circular ring when viewed from an end, although when viewed as in FIGS. 1 or 3 it is apparent that the cylindrical shape of the stent 10 is discontinuous. The importance of this feature is illustrated by a comparison of FIGS. 3 and 4.

In FIG. 3, the stent 10 is shown secured around a catheter 22, which has an inflatable balloon 23 adhered thereon surrounding a feed orifice 22*a* in the catheter. The balloon used in this embodiment is a folded balloon in which flaps 23*a* of the balloon 23 are folded over the catheter 22, as shown in FIG. 3. The folded flaps 23*a* allow the balloon 23 to inflate to a specific diameter without excessively stretching the balloon material and risking a rupture of the balloon.

The stent is compressed about the catheter 22 and balloon 23 so that it assumes a contracted outer diameter 24, which is calibrated to allow insertion into a particular body passageway. The clockwise loops 15 and counter-clockwise loops 16 overlap in the region 20, and the spring stiffness of the wire keeps the stent in this position during insertion. The stent 10 remains in tight contact with the catheter 22 even as the assembly is delivered around curves and bends in a body passageway.

After the catheter and stent are fully inserted into the passageway, the balloon 23 is inflated to a diameter 25, which is calibrated to force the stent 10 into contact with the passageway inner surface and, at least in some cases, to expand the passageway. As the balloon is inflated, the clockwise and counter-clockwise loops 15 and 16 diverge circumferentially until the longitudinal overlap between loops is reduced to the region 21, shown in FIG. 4. Thus, the effective diameter of the stent 10 relative to the longitudinal axis 26 is increased without thermal expansion or application of torsional forces to the stent, as suggested in the prior art.

In the best mode of the invention, the wire comprising the stent 10 is made of a malleable material, preferably from the group comprising annealed stainless steel, tantalum and platinum. This malleable material is sufficiently deformable to allow the loops 15 and 16 to diverge due to radially outward pressure applied by inflation of the membrane that comprises the standard balloon catheter. Because the stent material is plastic, rather than elastic, the stent retains the enlarged diameter after the balloon 23 is deflated and the catheter 22 removed. However, the material has sufficient strength and stiffness to avoid the stent being displaced on the balloon during insertion and to avoid the loops 15 and 16 being forced into an overlying relation. Further, the stent has sufficient strength and stiffness to allow it to maintain its position in the passageway and to resist being dislodged after the catheter 22 has been removed and the balloon is no longer stabilizing the stent. One example of a suitable wire has an outer diameter of 0.0018 inches and is stainless steel AISI 316 alloy.

It is desirable that the overlap region 20 in the contracted condition be sufficiently large so that the stent has a high contact area with the catheter, providing additional protection against the stent becoming dislodged while the assembly is inserted. In the expanded condition, the overlap region 21 should be sufficiently large to provide continuous circumferential support for the passageway in which the tent is inserted. In one example of the invention, the overlaying region 20 extends almost 360° circumferentially. For clarity, the illustrated embodiment shows the overlap 20 to be substantially less.

It can be observed that applicant's preferred embodiment can be dissected into single coil helical sections. FIG. 5 is an exploded view of a wire stent 49 having a longitudinal axis 50. The clockwise direction, according to a right-hand rule, is denoted by the heavy arrow 48 about the axis 50. The stent 49 comprises a series of alternating single coil clockwise helical sections 51 and single coil counter-clockwise helical sections 52. The helical sections 51 and 52 have forward ends 51*a* and 52*a*, and aft ends 51*b* and 52*b*, respectively. The adjacent helical sections are joined by cusps 53, with the forward end of one helical section being connected to the aft end of the next helical section. Thus, end 51*a* of the clockwise helical section 51 is joined to end 52*b* of the counter-clockwise helical section 52, while end 52*a* is connected to end 51*b*.

In a method of using the stent of the present invention, a stent and balloon catheter assembly 80 is inserted into a passageway 72, such as an artery, in a patient's body 70, as shown in FIG. 6. The assembly 80 is in the deflated configuration as it is maneuvered around the curve 76 in the passageway 72. The stiffness of the catheter 82 allows the assembly 80 to follow the curve 76, while the strength and stiffness of the stent 84 keeps it tightly engaged on the catheter balloon 86 during Insertion. The passageway has an occlusion situated at another bend in the passageway.

In FIG. 7, the stent and balloon catheter assembly 80 is shown fully inserted into the passageway 72 so that the stent 84 and balloon 86 are situated directly adjacent the occlusion 74 and following the curve of the passageway. The assembly is shown in the expanded configuration 80' in FIG. 8, in which the balloon 86' is inflated and the wire stent 84' expanded to contact and enlarge the passageway 72. The expansion is exaggerated in FIG. 8 for clarity. The assembly is expanded a sufficient amount to remove the occlusion 71 (FIG. 7) and open the passageway. The balloon is then deflated and the catheter removed, leaving the stent to hold the passageway open.

The method of the present invention concerns a process for fabricating a stent. Referring to FIG. 9, wire 30 is bent into a planar serpentine shape. The shape includes a series of straight sections 33 joined by bends or cusps 35. After the forming procedure has occurred, the straight sections 33 become curved sections 11, and cusps 35 become 13. Also, the portions of wire 30 on either side of the centerline 31 become the clockwise and counter-clockwise loops 15 and 16. as designated in FIG. 9. Free end 60 can be formed into a loop, such as loop 18 in FIG. 1.

A forming die 39 comprises a flat plate 40 having a straight trough 42 formed therein. In the cross-sectional view of FIG. 10, it is seen that the trough 42 has a semi-circular surface 43. The wire 30 is placed flat upon the plate such that the centerline 31 is coincident with the centerline of the trough 42.

The wire 30 is pressed into the trough 42 and against the semi-circular surface 43 using a forming bar 45, as shown in FIG. 11 and 12. The forming bar 45 is held in place by elastic bands 46. The ends of the loops 15 and 16 project upwardly or outwardly from the trough 42 and above the surface of the flat plate 40. In the next step of the present method, pulling tools 47 are used to pull the loops 15 and 16 over the exposed surface 45*a* (FIG. 12) of the forming bar 45, as shown in FIGS. 13 and 14. Hooks 47*a* at the end of pulling tools 47 engage the cusps 13 of the loops 15 and 16 during this pulling step. Next, the partially formed stent is removed from the plate 40 by lifting the forming bar away from the plate. The bar 45 is removed, leaving the configuration of the partially formed stent at this point is as shown in FIG. 15.

The balloon catheter 22 is inserted through the longitudinal cylindrical opening 12 in the stent 10, as shown in FIG. 15, and the ends of the loops 15 and 16 are pressed into contact with the catheter, as shown in FIG. 3. As mentioned, when the loops 15 and 16 are in their final overlapping position, it is preferred that they overlap a substantial amount. In one example of the invention, this overlap 20 (FIG. 3) is about 360 degrees. The balloon catheter used could be of various designs, such as the design shown in the patent to William A. Cook, U.S. Pat. No. 4,637,396, or as available from Cook, Inc. of Bloomington, Ind., under their catalogue number OMG 4.0–4.5 and 5.3FR catheter.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative in character, it being understood that only the preferred embodiment has been shown and described.

What is claimed is:

1. A method for inserting a stent which comprises:
(a) engaging a stent, having a longitudinal length, around a balloon catheter,
(b) locating the catheter and stent within a passageway, and
(c) inelastically expanding the stent, while maintaining the longitudinal length of the stent, by inflating the balloon catheter within the stent to inelastically deform the stent until the stent engages the passageway.

2. An apparatus for intraluminally reinforcing the lumen of a body passageway, comprising:
a tubular shaped stent formed by a plurality of connected elongate members having a first diameter which permits delivery of the tubular shaped stent into the lumen of the body passageway;
at least a portion of said tubular shaped stent having a second, expanded diameter, said portion being formable to said second diameter, without any change in length of said tubular shaped stent, upon application from the interior of said tubular shaped stent of an outwardly extending force, to expand said lumen and to retain said portion of said tubular shaped stent with said second, expanded diameter within said body passageway upon removal of said outwardly extending force.

3. A method for expanding the lumen of a body passageway comprising the steps of:
(a) inserting an endovascular stent, having a longitudinal length, disposed upon a catheter into the body passageway until it is disposed adjacent the lumen; and
(b) expanding a portion of the catheter to expand the endovascular stent outwardly into contact with the body passageway, by inelastically deforming a portion of the endovascular stent, while maintaining the longitudinal length of the stent, until the lumen has been expanded.
whereby the endovascular stent prevents the body passageway from collapsing and the endovascular stent remains in the body passageway.

* * * * *

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The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 10, "status" below.

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1	5,041,126	183	960	----	07/244,669	08/20/91	09/14/88	04	NO	PAID

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E180	A signature to the small entity statement is omitted.
E181	A small entity statement from each joint inventor has not been received.
E182	A small entity statement from the assignee or licensee has not been received.
E183	The requirements for filing as an independent inventor have not been met. See 37 CFR 1.9(c).
E 184	The requirements for filing as a small business concern have not been met. See 37 CFR 1.9(d).
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E186	The small entity statement was not verified by an oath or a declaration.

8032G

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Cesare Gianturco

Serial No. 244,669

Filed September 14, 1988

ENDOVASCULAR STENT AND DELIVERY SYSTEM

Before the Examiner

R. Lewis

Group Art Unit 336

TERMINAL DISCLAIMER

Hon. Assistant Secretary and Commissioner of Patents and Trademarks

Washington, D. C. 20231

Dear Sir:

I, Thomas A. Osborne, the Vice President of Cook Incorporated, P. O. Box 489, Bloomington, Indiana 47402, represent that Cook Incorporated is the assignee and the exclusive owner of the entire right, title and interest of, in and to patent application Serial No. 244,669 filed September 14, 1988 for ENDOVASCULAR STENT AND DELIVERY SYSTEM.

Cook Incorporated hereby disclaims the terminal part of any patent granted on the above-identified application, which would extend beyond the expiration date of U.S. Patent No. 4,800,882 issued January 31, 1989 and hereby agree that any patent so granted on the above-identified application shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to United States Patent No. 4,800,882, this agreement to run with any patent granted on the above-identified application and to be binding upon the grantees, their successors or assigns.

Enclosed is $100.00 as payment of the fee for a disclaimer (37 CFR §1.20(d)).

COOK INCORPORATED

December 31, 1990
Date of Signature

By: Thomas A. Osborne
Thomas A. Osborne, Vice President